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NOTICE OF ALLOWANCE AND FEE(S) DUE

28213

7500

02/17/2009

DLA PIPER LLP (US) 4365 EXECUTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121-2133

EXAMINER				
CHOWDHURY, IQBAL HOSSAIN				
ART UNIT	PAPER NUMBER			

1652 DATE MAILED: 02/17/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,110	04/19/2006	Gregory I. Frost	DELIA1330-1	9011

TITLE OF INVENTION: HUMAN CHONDROITINASE GLYCOPROTEIN (CHASEGP), PROCESS FOR PREPARING THE SAME, AND

PHARMACEUTICAL COMPOSITIONS COMPRISING THEREOF

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	05/18/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where ar in m

appropriate. All further correspondence including the Patent, advance orders and notification indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new of maintenance fee notifications. CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) 28213 7590 02/17/2009 DLA PIPER LLP (US) 4365 EXECUTIVE DRIVE SUITE 1100			Note: A certificate of mailing can only be used for domestic mailings of the				
			ŗ	papers. Each additional paper, such as an assignment or formal drawing, mus have its own certificate of mailing or transmission. Certificate of Mailing or Transmission I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.			
			I S a t				
SAN DIEGO, C	A 92121-2133						(Depositor's name)
							(Signature)
			Į.				(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENT	OR	ATTC	RNEY DOCKET NO.	CONFIRMATION NO.
10/539,110	04/19/2006		Gregory I. Frost			DELIA1330-1	9011
TITLE OF INVENTION PHARMACEUTICAL C			PROTEIN (CHASEGI			PARING THE SAM	E, AND
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DU	JE PREV. PAID ISS	JE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0		\$1055	05/18/2009
EXAM	IINER	ART UNIT	CLASS-SUBCLASS				
CHOWDHURY, I	QBAL HOSSAIN	1652	435-200000				
CFR 1.363). Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON PLEASE NOTE: Unless an assignee is identified below, no assignee recordation as set forth in 37 CFR 3.11. Completion of this form is NO (A) NAME OF ASSIGNEE		or agents OR, altern (2) the name of a si registered attorney 2 registered patent a listed, no name will THE PATENT (print or data will appear on th	ata will appear on the patent. If an assignee is identified below, the document has been filed for a substitute for filing an assignment.				
4a. The following fee(s) Issue Fee Publication Fee (N	are submitted:	permitted)	b. Payment of Fee(s): (I A check is enclose Payment by credit	Please first reapply : d. card. Form PTO-203	any prev	viously paid issue fee	
	# of Copies		overpayment, to D	eby authorized to ch eposit Account Num	ber	required fee(s), any de	n extra copy of this form).
5. Change in Entity Sta a. Applicant claim	i tus (from status indicate is SMALL ENTITY stati	· · · · · · · · · · · · · · · · · · ·	☐ b. Applicant is no	longer claiming SMA	ALL EN	TITY status. See 37 CI	FR 1.27(g)(2).
NOTE: The Issue Fee an	d Publication Fee (if rea		d from anyone other tha				e assignee or other party in
Authorized Signature				Date			
Typed or printed name							
This collection of inform an application. Confiden submitting the complete this form and/or suggest Box 1450, Alexandria, V Alexandria, Virginia 223	tiality is governed by 35 d application form to the ions for reducing this bu. Virginia 22313-1450. DC	CFR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the O NOT SEND FEES OR	on is required to obtain 1.14. This collection is 7 depending upon the ir 10 de chief Information Of 11 COMPLETED FORMS	or retain a benefit by estimated to take 12 dividual case. Any of ficer, U.S. Patent and TO THIS ADDRES	the pub minute commen d Trader SS. SEN	lic which is to file (and s to complete, includin ts on the amount of tir mark Office, U.S. Dept D TO: Commissioner	by the USPTO to process) g gathering, preparing, and me you require to complete artment of Commerce, P.O. for Patents, P.O. Box 1450,

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

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DLA PIPER LLP (US)		CHOWDHURY, I	QBAL HOSSAIN	
4365 EXECUTIVE DRÍVE			ART UNIT	PAPER NUMBER
SUITE 1100 SAN DIEGO, CA 92121-2133			1652 DATE MAILED: 02/17/200	9

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)	
	10/539,110	FROST ET AL.	
Notice of Allowability	Examiner	Art Unit	_
	 IQBAL H. CHOWDHURY	1652	
The MAILING DATE of this communication appear All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIPLY of the Office or upon petition by the applicant. See 37 CFR 1.313 1. This communication is responsive to 1/8/09: 12/19/08.	(OR REMAINS) CLOSED in this or other appropriate communic IGHTS. This application is subjection	s application. If not included ation will be mailed in due course. THIS	e
2. X The allowed claim(s) is/are <u>1, 3-8, 13-14, 16, 50, 51, 53-56</u>	<u>and 58</u> .		
 3. Acknowledgment is made of a claim for foreign priority ur a) All b) Some* c) None of the: 1. Certified copies of the priority documents have 2. Certified copies of the priority documents have 3. Copies of the certified copies of the priority documents 	been received. been received in Application N	o	
International Bureau (PCT Rule 17.2(a)).			
* Certified copies not received: Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be submin INFORMAL PATENT APPLICATION (PTO-152) which give	IENT of this application. itted. Note the attached EXAMII	NER'S AMENDMENT or NOTICE OF	
 CORRECTED DRAWINGS (as "replacement sheets") mus (a) ☐ including changes required by the Notice of Draftspers 		DTO 049) ottochod	
(a) ☐ including changes required by the Notice of Dranspers 1) ☐ hereto or 2) ☐ to Paper No./Mail Date	,	-10-946) attached	
(b) ☐ including changes required by the attached Examiner's Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t	s Amendment / Comment or in t	rawings in the front (not the back) of	
6. DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT	sit of BIOLOGICAL MATERI	AL must be submitted. Note the	
 Attachment(s) 1. ☐ Notice of References Cited (PTO-892) 2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 9/08; 2/08 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material 	6.	l Date	

DETAILED ACTION

Application Status

Claims 1-8, 10-14, 16-21, 23-56 and 58 are currently pending in this application.

In response to a previous Office action, a non-final action (mailed on March 24, 2008), Applicants filed an amendment on January 8, 2009, and amending claims 1, 50-51 and 58 is acknowledged. Claims 2, 10-11, 17-21, 23-49 and 51-56 remain withdrawn as encompassing non-elected inventions.

Claims 1, 3-8, 12-14, 16, 50 and 58 are under consideration.

Election/Restriction

Previously Restriction requirement mailed on 10/3/2007 between proteins of SEQ ID NO: 1, 2 and 6, wherein SEQ ID NO: 1 and 6 are human origin of full length and truncated chondroitinase glycoprotein is hereby withdrawn because both the sequences are structurally related and have same function. But Restriction requirement between SEQ ID NO: 1 or 6 and 2, wherein SEQ ID NO: 2 is mouse origin is structurally and functionally independent and distinct. Therefore, Restriction between SEQ ID NO: 1 or 6 and 2 is maintained. Claims reciting SEQ ID NO: 2 remain withdrawn as encompassing non-elected inventions.

Claims 1, 3-8, 12-14, 16, 50 and 58 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 51, 53-56 are directed to the process of using the allowable product, previously withdrawn from

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consideration as a result of a restriction requirement, mailed on 10/3/2007 is hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 23-49 directed to the invention(s) II-V not requiring all the limitations of the allowable product claim, have NOT been rejoined.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, the restriction requirement of Groups I and VI as set forth in the Office action mailed on 10/3/2007 hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in several telephone interviews with Lisa Haile, applicants' representative, between December 23, 2008 and January 31, 2009..

Amend claims as shown bellow:

- Claim 1 A substantially purified soluble mammalian chondroitinase glycoprotein (CHASEGP) comprising as set forth in SEQ ID NO:6.
- Claim 14 The glycoprotein of claim 1, wherein the polypeptide is encoded by a the nucleic acid sequence as set forth in SEQ ID NO. 5.
- Claim 51 A method for treating a subject suffering from an excess of CHASEGP substrate <u>produced from a scar tissue</u>, comprising <u>administering the glycoprotein of claim 1 to the subject</u> in an amount sufficient to remove said CHASEGP substrate.
- Claim 53 The method of claim <u>512</u>, wherein the scar tissue is a glial scar resulting from spinal cord injury.
- Claim 54 The method of claim 521, wherein the scar tissue is a result of surgery.
- Claim 55 The method of claim $5\underline{12}$, wherein the scar is a keloid scar.
- Claim 56 A method for treating a subject suffering from an excess of

CHASEGP substrate The method of claim 51 wherein the substrate is associated with a

herniated disk comprising administering the glycoprotein of claim 1 to the subject in an

amount sufficient to remove said CHASEGP substrate.

Cancel claims 2, 10-12, 17-21, 23-49, 52 and 57.

Allowable Subject Matter

Claims 1, 3-8, 13-14, 16, 50, 51, 53-56 and 58 are allowed.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: The applicant has claimed a substantially purified soluble mammalian chondroitinase glycoprotein (CHASEGP) as set forth in SEQ ID NO: 6 encoded by the nucleic acid sequence as set forth in SEQ ID NO:5 and a composition comprising a said soluble chondroitinase glycoprotein (CHASEGP) of SEQ ID NO: 6 and a method of treating a subject using soluble chondroitinase glycoprotein (CHASEGP) of SEQ ID NO: 6. The prior art does not teach an isolated protein having the amino acid sequence shown in SEQ ID NO: 6 or a composition comprising said polypeptide. The claimed invention is novel and nonobvious over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury, Ph.D. whose telephone number is

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(571) 272-8137. The examiner can normally be reached on Monday-Friday from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed, can be reached at (571) 272-0934.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Iqbal Chowdhury, Patent Examiner Art Unit 1652 (Recombinant Enzymes) US Patent and Trademark Office Rm. REM 2B69, Mail Box. 2C70 Ph. (571)-272-8137, Fax. (571)-273-8137

/Nashaat T. Nashed/ Supervisory Patent Examiner, Art Unit 1652